Docket No. DEP-5172USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Hassan Serhan et al. Group Art Unit: 3733
Serial No.: 10/283,911
Filed: September 30, 2003 Examiner: A. R. Reimers
Title: METHODS AND DEVICES TO REPLACE SPINAL DISC NUCLEUS PULPOSUS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF HASSAN SERHAN UNDER 37 CFR 1.131

Sir:

I, Hassan Serhan, declare and state that:

1. I am Director of Research at DePuy Spine, Inc. (formerly DePuy AcroMed, Inc.) in Raynham, MA, and have held this position since 1999.

2. I received a Ph.D. in Mechanical Engineering from the University of Buffalo.

3. I am a co-inventor of the above captioned patent application and am aware that the present invention relates to methods and devices to replace spinal disc nucleus pulposus.

4. Attached hereto as Exhibit I is a copy of a 5 page invention disclosure related to the subject matter of the above captioned patent application. Specifically, Exhibit I is the invention disclosure upon which the subject patent application is based on. The date of the invention disclosure and other dates indicated within (all of which are redacted) are prior to the filing date of U.S. 2005/0113855 ("Kennedy, II").

5. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that will false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the instant patent application and any patent issuing thereon.

Respectfully submitted,

Hassan Serhan

9-21-2007 (Date)

EXHIBIT I

Disclosure No. _____
(For Patent Dept. Use)

INVENTION DISCLOSURE

1. **TITLE OF INVENTION** **Method and Device to Replace Disc Nucleus Pulposus**

2. **INVENTORS** (Person or persons who had the main idea or ideas relating to the invention.)

Full Name:	Hassan Serhan, Ph.D.	Michael Andrew Slivka	
Residence:	27 Forest Edge Rd	90 Lehner Drive	
	S. Easton, MA 02375	Taunton, MA 02780	
Citizen of:	USA	USA	
Bus. Phone:	(508) 828-3722	(508) 828-3639	
Supervisor:	Alex DiNello	Hassan Serhan	
Signature:			

(Use additional pages if there are more than three inventors.)

3. **PUBLIC USE**

Has the invention been in public use (non-confidential use outside BMC) for other than experimental purposes? (Scale up, product development, or any other public use aimed at bringing a product to market are not considered experimental.)
___NO___ If "yes", indicate the date of the first such use: _____

4. **SALE**

Has a product employing the invention been sold or offered for sale? ___NO__
If "yes", indicate the date of first such sale or offer for sale:_____

5. **PUBLICATION**

A. Has this invention been described in a printed publication (newsletter, patent journal article, etc.)? ____NO__ If "yes", indicate earliest date of publication _____; earliest date of submission of information to a publisher _____; and the name of the publication _____
_____.

B. Has the invention been shown, described or demonstrated to persons who are not obligated to keep the invention secret (such as vendors or consultants)? _____NO_____ If "yes", indicate the earliest date of such a showing, description or demonstration _____, and to whom (include country of recipient of information) _____

6. CONCEPTION

Invention conceived (realization of problem and solution) on .
In which country was the invention conceived? _____USA_____
Earliest witnessed and dated written evidence of conception is the attached signed and witnessed description dated:

7. ACTUAL REDUCTION TO PRACTICE

Has invention actually been fully constructed or demonstrated? _____NO_____
If "yes", indicated completion date _____. Earliest witnessed and dated written evidence of a demonstration of the invention is:

8. PROBLEM OVERCOME BY INVENTION *

Current surgical treatment options require highly invasive and lengthy procedures and the end result do not provide for restoration of the intervertebral joint range of motion. The SIS nucleus pulposus device is a biological solution that will remodel to restore joint flexibility, disc height and shock absorption of normal intervertebral disc.

The proposed SIS nucleus pulposus replacements have the potential to immediately restore motion and disc height, replace proinflammatory disc tissues and remodel to connective fibrocartilage tissues to stabilize the motion segment. This invention would allow the biological replacement of the nucleus through a trephine hole with low insertion loads following denucleation of the disc.

9. PURPOSE OF THE INVENTION (brief) *

Immediate restoration of disc height following complete removal of pro-inflammatory tissues can be achieved using SIS nucleus pulposus replacement devices. This invention would allow placement of the SIS device through a trephine hole and minimally invasive surgery. It would be stuffed into the denucleated disc with low insertion loads.

This invention will provide a biological solution for disc height restoration while using minimal invasive or less invasive procedure via SIS nucleus pulposus replacement device.

10. DESCRIPTION OF THE INVENTION (brief) *

This invention is a small intestinal submucosa (SIS) tape, strip, foam, pellets, cord or pillow like device that could be delivered, (stuffed or folded to allow insertion) through a small window in the annular ring post discectomy using manual or automated disc removal instrumentation. The SIS material could be cell seeded prior to implantation with MSCs, bone marrow or soaked in platelet rich plasma, growth factors such as MP52, TGFb etc. to enhance its biological remodeling. Additionally, the vertebral endplates may be decorticated to allow adequate nutritional supply for the SIS remodeling.

11. BRIEF DESCRIPTION OF STATE OF THE ART *

Spine fusion procedures present state of the art treatment for disc problems, which generally involves the use of interbody fusion cages and spinal fixation systems to stabilize the fusion site.

Few disc prosthesis devices and nucleus pulposus augmentation devices are being investigated on a limited basis. The nucleus pulposus augmentation devices being evaluated are either in situ cured (in-situ cured polyurethane contained in a bag and in-situ cured protein polymers) or relatively solid hydro-gels (Ray Medical hydro-gel in UHMWPe pillow and Howmedica hydro-gel ball). In situ cured nucleus pulposus augmentation devices have the potential to exude out of the disc space intra-operatively.

This invention would allow the removal of the nucleus and replace the degenerated nucleus with tissue friendly biocompatible material derived from porcine small-intestinal submucosa (SIS) as soft tissue implant or a collagen scaffold that will restore disc height and maintain the motion.

12. DIFFERENCES BETWEEN PRIOR ART AND THIS INVENTION *

This invention differs from prior art because 1) during spinal movements the device has a greater probability of maintaining its location with the disc space due to tissue incorporation "biological incorporation". 2) Restores disc height and function with pulposus augmentation using MIS procedure. 3) stabilize the motion segment by SIS remodeling to stable connective tissues.

Related patents: US5922028, US5755797, US20030004574, US20020049498, WO2003007854, US20020133231, WO0176654, US20020147497, US20020103542

13. DETAILED DESCRIPTION

This device is a small intestinal submucosa (SIS) tape, strip, cord, pellets, foam, fibers or pillow-like device that could be stuffed or folded to allow insertion through a trephine hole in the annular ring post discectomy. Discectomy could be performed using manual or automated disc removal instrumentation.

Using a 3-8 mm trephine (preferably 5mm), a portal in the annulus will be made followed by a thorough discectomy. A strip of SIS will be packed into the disc such that the inner cavity is filled but no SIS material is protruding from the annulus. Packing of the SIS strip could be facilitated through a continuous feed gun operated from outside of the patient that allows easy SIS insertion and prevents backing out during insertion.

In one embodiment, SIS spheres, pellets or fibers are delivered to the disc space through a cannula. The tip of the cannula may preferably allow delivery of the SIS in variable directions, thus facilitating complete filling of the disc space. In a preferred embodiment, the tip of the cannula is curved and rotatable. In another preferred embodiment, the tip is made of a shape-memory alloy and is able to be straightened upon retraction into an outer cannula, thus allowing easier surgical insertion.

In another embodiment, SIS devices could be supplied in pre-filled, sterile cartridges for easy attachment to delivery devices.

In one embodiment, the SIS device is soaked or suspended in platelet-rich plasma, then combined with thrombin prior to implantation such that a stable clot will form and thus resist SIS extrusion.

The SIS material could be cell seeded prior to implantation with MSCs, bone marrow or soaked in platelet rich plasma, growth factors such as MP52, TGFb etc. to enhance its biological remodeling. Additionally, the vertebral endplates may be decorticated "curretted/picked" to cause bleeding into the disc space to allow adequate nutritional supply for the SIS remodeling.

Questions marked with "*" may be answered in more detail on attached pages. Detailed answers to questions 11 and 12 may be submitted at a later date; however, consideration of most Invention Disclosures will be delayed until these two questions are answered in detail. An answer to question 11 should include copies of patents, journal articles and product literature giving evidence of the state of the prior art. The typical "introduction" portion of a scientific paper is a good format to use in making a detailed response to questions 11 and 12.

Please indicate the number of pages attached to this form at the time of submission: _____0_____.

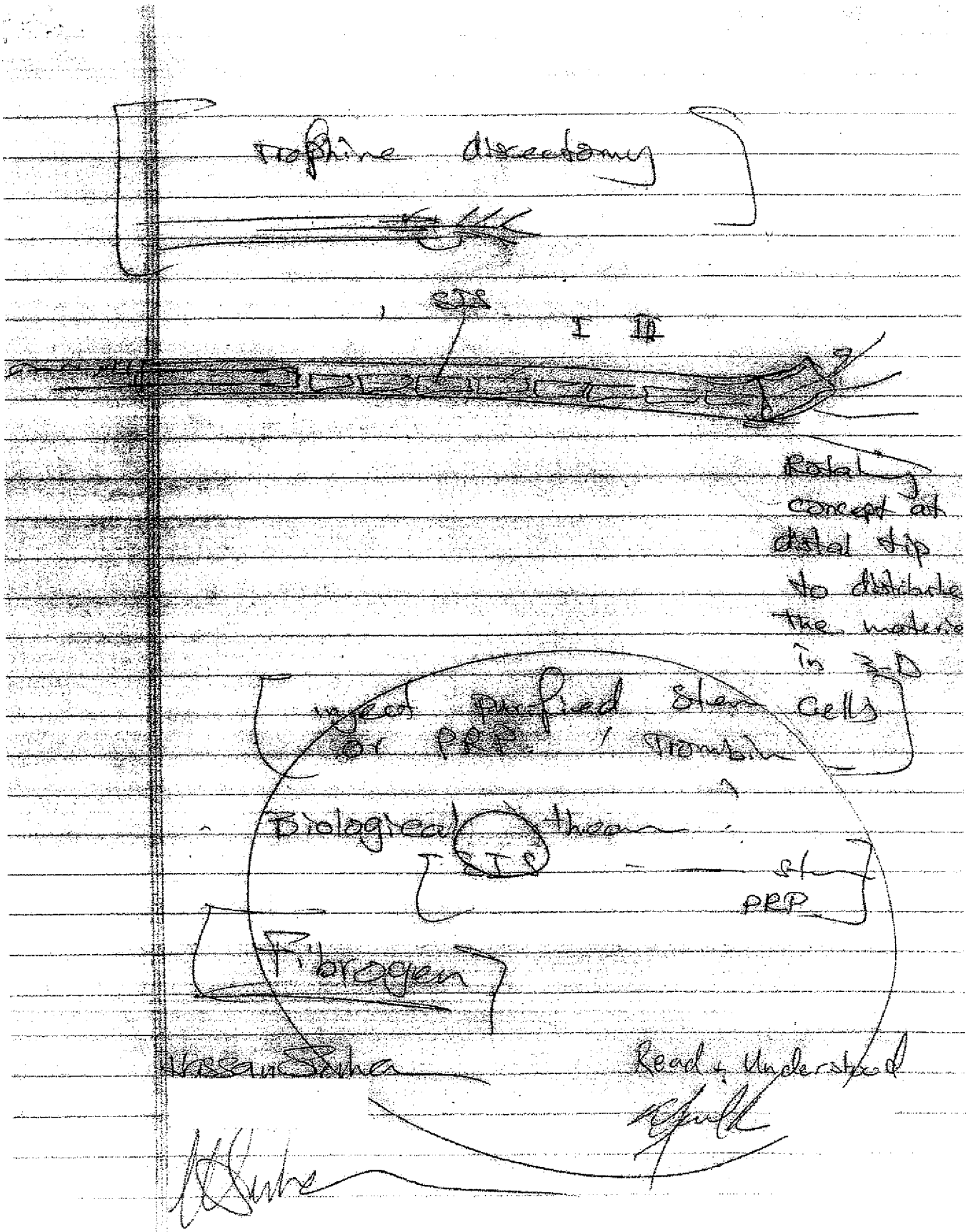
14. **WITNESSES:** (If possible, obtain signature of person(s) who witnessed and understood conception and test demonstration of items 5 and 6 above.)

1. The invention was first explained to me by the above described inventor(s) on ___ ___, and it is understood by me.

(Signature of Witness) (Date of Signature)

2. The invention was first explained to me by the above described inventor(s) on ___ ___, and it is understood by me.

(Signature of Witness) (Date of Signature)


Trephine discectomy
I II
Rotating concept at distal tip to distribute the material in 3-D
Injected Purified Stem Cells or PRP / Thrombin
Biological Mean
PRP
Fibrogen
Vikram Sinha
Read & Understood